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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,266

10/25/2005

Kenneth T. Douglas

39-317

2787

23117

7590

03/17/2009

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

03/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/554,266	<b>Applicant(s)</b> DOUGLAS ET AL.	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☒ Claim(s) 8, 19-22, 24, 29, 35 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This application is a 371 of PCT/GB04/01803, filed April 23, 2004. The international search report and international preliminary examination report for the PCT application have been received and considered.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group II, claims 3-46, in the reply filed on November 25, 2008 is acknowledged. Upon further consideration, the election/restriction requirement mailed July 25, 2008 is **withdrawn**. Accordingly, claims 1-46 have been examined.

### ***Information Disclosure Statement***

3. The information disclosure statement filed October 25, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that some of the "other documents" cited on the IDS were retrieved during the examiner's search and are therefore cited herein on a Form 892. The cited international search report has been considered (as indicated above) but has been lined through because the provided date is not a publication or public availability date. The other non-patent literature references, copies of which were not provided, have not been considered. It is noted that the Form PCT/DO/EO/903 mailed to applicant on October 31, 2007 did not indicate that the cited references were present in the application file (see MPEP 609.03).

4. It is also noted that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### ***Oath/Declaration***

5. Regarding the oath/declaration filed February 27, 2006, it is noted that the oath/declaration includes an improper claim under 35 USC 120 to PCT/GB04/01803. However, the oath/declaration also indicates that the instant application is a 371 of the PCT application, and the application was filed and has been accepted as a 371. Accordingly, the record is clear with regard to the status of the application as a 371 application, and the oath/declaration is therefore acceptable.

#### ***Drawings***

6. The drawings are objected to because only some of the drawings have been properly identified by a "Figure" number, and it appears that the assignment of numbers to the first several figures (which presently are unlabeled) may alter the numbering of all of the drawings. (Applicant's attention is also drawn to the objection below related to the lack of a description for the figures).

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

8. The specification is objected to because it does not contain, as a separate section, a brief description of the drawings. Amendment of the specification to include a separate section briefly describing the content of each of the drawings, as set forth in 37 CFR 1.74, is required.

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Particularly, it is noted that the claims are directed to methods rather than products.

***Claim Objections***

10. Claim 8 is objected to because of the following informalities: the claim recites “A method as claimed in 7” rather than, e.g., “A method as claimed in claim 7”.

Appropriate correction is required.

Claims 19-22 are objected to because of the following informalities: the claims recite “said after step (a)” rather than “said heating after step (a)”. Appropriate correction is required. Applicant’s attention is also directed to the need to provide proper antecedent basis for the use of the term “step”; see rejection under 35 USC 112, second paragraph, below.

Claims 24 and 29 are objected to because of the following informalities: the term “polynucleotide” is misspelling in claim 24. Appropriate correction is required.

Claims 35 and 38 are each objected to because of the following informalities: the claims do not end in a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112, second paragraph***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 provides for the use of an organic solvent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of or comprising hybridization. It is noted that the claims are drawn to a method of analysis "which is a nucleic acid hybridisation assay involving detection of an exciplex in a medium containing exciplex forming partners." However, the claims do not otherwise reference hybridization, and it is not clear how the recited method steps actually relate to the required "nucleic acid hybridisation assay". Accordingly, clarification is required.

Claims 3-6 are also indefinite over the recitation of the limitation "the appropriate wavelength" in independent claim 3. The language of the claim does not clear what the recited wavelength is to be "appropriate" for, or otherwise apprise an artisan as to the

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type of wavelength(s) that would be embraced by the claims. Accordingly, this language lacks clear boundaries, rendering the claims unclear and indefinite.

Regarding claim 4, the phrase "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 7-46 are indefinite over the recitation of the limitation "the second chromophoric moiety" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

Claims 7-46 are also indefinite because it is unclear whether the claims are drawn to a method detecting "for formation of an exciplex" as indicated in the final method step of independent claim 7, or to a method of "analysing a sample to determine the presence or otherwise therein of a target polynucleotide sequence," as set forth in the claim preamble. The language of the claim does not make clear the relationship between the "detecting" step and determination of the presence or absence of the target sequence.

Claims 15-22 all recite the limitation "step (a)". However, there is insufficient antecedent basis for this limitation in the claims, because claim 7, while referring to "(a)", does not refer to "(a)" as a "step". Accordingly, it is suggested that claim 7 be amended such that it employs the term "step(s)".

Regarding claim 18, the term "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention, and the extent to which the limitation(s) following that term limit the claim.



Claims 31-32 are indefinite over the recitation of the limitations "the oligonucleotide probes", "the target nucleic acid", and "the adjacent 3' and 5' ends" in claim 31. There is insufficient antecedent basis for these limitations in the claims.

Claim 37 is indefinite because it is unclear how the claim further limits claim 36 to the extent that claim 36 does not require a "nucleic acid analogue." Applicant is reminded that a proper dependent claim must further limit the claim(s) from which it depends. This rejection could be overcome by amending claim 37 to state "wherein the target polynucleotide sequence comprises a nucleic acid analogue, and wherein said analogue is a PNA or LNA".

Claim 43 is indefinite over the recitation of the limitation "the target and probe strands". There is insufficient antecedent basis for this limitation in the claims.

Claims 44-46 are indefinite over the recitation of the limitation "the target nucleic acid" in claim 44. There is insufficient antecedent basis for this limitation in the claims.

Claims 44-46 are also indefinite over the recitation of the limitation "(but not all)" in claim 44 in parenthesis, because it is not clear to what extent the material in parentheses limits the claims (for example, is this recitation given equal weight or less weight as compared to other claim limitations?). The claim should be rewritten in a manner that does not employ parenthesis, such that the limitations on the claimed subject matter are clear.

Claims 45-46 are indefinite over the reference in claim 45 to "immobilization...on a" liquid substrate. It is not clear what is meant by this recitation, and neither the specification nor the prior art provide a clear definition for what would be meant by

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immobilization “on a liquid” within the context of the claimed invention. Accordingly, clarification is required.

Claim 46 is indefinite over the recitation of the limitation “ ‘chip’ “ in the claim. It is not clear how the use of quotation marks in the claim is intended to further limit or alter the meaning of the term “chip”.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Deere et al (Letters in Applied Microbiology 27:352-356 [1998]).

The claim is drawn to the "use of an organic solvent selected from 2,2,2-trifluoroethanol, ethylene glycol or ethylene glycol dimethyl ether for enhancing formation, potential formation, fluorescence and/or detection of an exciplex in a nucleic acid hybridization assay". Deere et al disclose the use of ethylene glycol in a probe spacer arm, and disclose that this use of ethylene glycol enhances fluorescent signals in a hybridization assay (see entire reference, particularly the abstract). Accordingly, Deere et al anticipate the claim.

Applicant's comments regarding the Deere et al reference in the reply of November 25, 2008 are noted. However, the instant claim encompasses any manner of “use” of ethylene glycol in enhancing fluorescence in a nucleic acid hybridization assay,

and the use of the reagent in the spacers taught by Deere et al constitutes such a use. Accordingly, Deere et al anticipates the claim.

17. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemp et al (Journal of Organic Chemistry 68(8):3009-3016 [March 2003]), as evidenced by the National Library of Medicine Medical Subject Heading ("MeSH") entry for "trifluoroethanol" (2009).

It is again noted that claims 1-2 are improper process claims and are indefinite in reciting a use without any active, positive steps delimiting how this use is actually practiced. Thus, it appears that the claims may broadly encompass any "use" of any the recited reagents 2,2,2-trifluoroethanol, ethylene glycol or ethylene glycol dimethyl ether. This rejection applies to the claims to the extent that they are drawn to such a use.

Lemp et al disclose the use of trifluoroethanol in photooxygenation reactions (see entire reference, particularly Table 1). The MeSH entry establishes that the term "trifluoroethanol" references 2,2,2-trifluoroethanol (see entire reference), providing extrinsic evidence of an inherent feature of the reagent employed by Lemp et al. Accordingly, as Lemp et al disclose the use of 2,2,2-trifluoroethanol, Lemp et al anticipate claims 1-2.

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Douglas et al (US 6,475,730 B1 [November 2002]), Davies et al (US 6,902,900 B2 [June 2005]), and Bruce et al (WO 03/043402 A2 [May 2003]) each

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disclose hybridization assays in which exciplex formation is employed during detection; however, the references do not disclose or suggest the use of the organic solvents of the instant invention. It is additionally noted that the post-filing date reference of Bichenkova et al (Biochem. Biophys. Res. Comm. 332;956-964 [2005]) discloses aspects of the claimed invention.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Diana B. Johannsen/  
Primary Examiner, Art Unit 1634